Background Information from Congressman Joe Pitts

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202 225-2411

Thursday, August 04, 2005
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The Medical Device User Fee Stabilization Act of 2005

On Monday, July 25, 2005 Congressman Joe Pitts introduced H.R. 3423, the Medical Device User Fee Stabilization Act of 2005.

This legislation will be on the House floor as early as 1:30 p.m. today, July 26, 2005.

▪ MEDICAL DEVICE USER FEE AND MODERNIZATION ACT (MDUFMA)

In 2002, Congress unanimously passed The Medical Device User Fee and Modernization Act (PL 107-250) to give FDA additional funds and expertise to help provide *timely* patient access to new medical technologies.

MDUFMA creates a stable and sufficient funding base for the Food and Drug Administration (FDA) through industry paid user fees ($150 million) and increased Congressional appropriations ($75 million) over five years. MDUFMA will need to be reauthorized for FY 08.

Modeled after a similar program used to approve medicines and pharmaceuticals, this legislation was passed to address concerns over the pace of the FDA's lengthy review process and the need for consumers to have more access and choice in a shorter period of time.

This law replaced the entirely government-funded device review process with a system partially funded with fees paid by the manufacturers of the new technologies. Because of this legislation, the device approval time has been virtually cut in half.

▪ THE "TRIGGER"

To ensure that fees are additive and that the Agency receives all of the funding envisioned over the five year period, a "trigger" in MDUFMA terminates the user fee program on September 30, 2005 if the resources prescribed in the law are not realized.

While Congress provided the $216.7 million required by MDUFMA for FY05, the funding is $40 million below the MDUFMA target due to shortfalls in FY03 and FY04.

To prevent the "trigger" from sun-setting the program in September, Congress must amend MDUFMA to reduce the appropriations target for the program over the five year period.

THE MEDICAL DEVICE USER FEE STABILIZATION ACT OF 2005

Section 738 of the Food, Drug and Cosmetic Act (Authority to Assess and Use Device Fees), is amended by:

- Setting premarket application (PMA) fees at $259,600 for 2006 and $281,600 for 2007, which is an 8.5% increase each year (to provide stability in cost increases for companies submitting applications).
- Permitting FDA to use up to two-thirds of fees carried over from previous years in order to keep the program going. FDA must notify Congress if it intends to do this.
- Setting the small business threshold at $30 million (where it is now) for the purposes of a first-time waiver of the PMA fee.
- Raising the small business threshold to $100 million for the purposes of all other applications, reports, and supplements.
- Requiring additional information in FDA's medical device program annual report on the number and types of applications received by size of small business up to the new small business threshold.
- Requiring a certification by the Secretary in FDA's annual report that funds appropriated for other purposes are not diverted for device review.
- Amends Section 502 (u) regarding labeling and tracking of reprocessed medical devices intended for single use by the original manufacturer. Requires reprocessors to mark the device if the original manufacturer marks the device. If the original manufacturer does not mark the device, the reprocessor must still mark the device but can mark using a detachable label that is affixed to a patient's medical record.